Complete Summary

GUIDELINE TITLE

Aspects of primary care for the HIV-infected substance user.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2009 Feb. 16 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2004. 17 p. [36 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Substance use
- Viral hepatitis (i.e., hepatitis A, B, C)
- Tuberculosis, including latent tuberculosis infection (LTBI)
- Sexually transmitted diseases (e.g., syphilis, genital ulcers, gonorrhea, chlamydia)
- Soft tissue infections (abscesses)

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To provide primary care recommendations on selected conditions that may have greater prevalence among human immunodeficiency virus (HIV)-infected substance users, or that may have particular diagnostic, preventive, or therapeutic implications in this diverse patient population

TARGET POPULATION

- Human immunodeficiency virus (HIV) infected substance users and their drug sharing, sexual, and household contacts
- Intravenous drug users

INTERVENTIONS AND PRACTICES CONSIDERED

Viral Hepatitis

1. Prevention
    - Screening for hepatitis A, B, C including hepatitis B virus serologies and hepatitis A and C immune globulin
    - Hepatitis A vaccine
    - Hepatitis B vaccine
    - Combined hepatitis A and B vaccine

- Vaccination of drug-sharing, sexual, and household contacts
- Risk reduction counseling for hepatitis A, B, and C
- Referral to sources of sterile-injection equipment (e.g., Syringe Exchange Programs and Expanded Syringe Access Demonstration Program)

2. Evaluation of chronically infected or co-infected hepatitis patients for liver disease
3. Counseling hepatitis C patients to discontinue alcohol consumption
4. Identification of barriers and consideration of measures to promote adherence

Tuberculosis

1. Tuberculin skin test (TST), known as purified protein derivative (PPD)
2. Detailed history, physical examination and chest radiograph
3. Expedited treatment
4. Directly observed therapy (DOT)
5. Pharmacotherapy:
    - Isoniazid
    - Pyridoxine
    - Rifampin/pyrazinamide (not recommended for latent tuberculosis [TB] infection)
6. Monitoring of serum liver enzymes

Sexually Transmitted Infections (STIs)

1. Behavioral risk reduction counseling
2. Screening for syphilis, gonorrhea, and chlamydia at all sites of exposure (cervix, rectum, pharynx, urethra)
3. Diagnosis (of syphilis)
    - Non-treponemal tests
    - Treponemal tests (recommended)
    - Fluorescent treponemal antibody-absorption (FTA) tests

Soft-Tissue Disorders

1. Counseling on risk reduction for soft-tissue infections
2. Draining and packing abscesses
3. Culture and sensitivity testing when pus can safely be obtained

MAJOR OUTCOMES CONSIDERED

- Incidence of viral hepatitis infection in human immunodeficiency virusÂ (HIV)-infected substance usersÂ Â
- Incidence and onset of late hepatic sequelae
- Hepatitis C treatment adherence
- Rates of tuberculosis infection (active and latent)
- Rates of sexually transmitted diseases
- Prevalence of abscesses
- Efficacy of risk-reduction interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use

of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost analyses were reviewed.

For substance users in methadone maintenance treatment programs, on-site directly observed therapy (DOT) may be a valuable adherence-promoting strategy and can be both cost-effective and cost-saving from a societal perspective. When feasible, incentives which offer positive reinforcement to substance users, including monetary incentives, seem to be both effective at increasing rates of adherence to tuberculosis (TB) services and justifiable on a cost basis. Similarly, directly observed therapy for latent tuberculosis infection may be used to increase completion rates in congregate settings (e.g., correctional and residential facilities, shelters) or in ambulatory clinical settings that are attended on a frequent basis (e.g., methadone maintenance programs, dialysis units).

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Viral Hepatitis

As part of the baseline assessment, clinicians should ask human immunodeficiency virus (HIV)-infected patients about their hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination history and should obtain the following:

- HBV serologies: hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (HBcAb) (immunoglobulin G [IgG] or total)
- Hepatitis A IgG and hepatitis C IgG

Clinicians should counsel patients about behavior modifications that decrease their risk of acquiring hepatitis infection through unprotected sexual activity and injection drug use.

Key Points:

- Substance users are at high risk for infection with HAV, HBV, and hepatitis C virus (HCV).
- Infection among substance users may initiate and increase the magnitude of hepatitis outbreaks.

Hepatitis A

Clinicians should administer the HAV vaccine to HIV-infected patients who are negative for HAV IgG. The full series, consisting of an initial dose and a second dose 6 to 12 months later, should be given to ensure maximal antibody response.

Clinicians should administer HAV vaccination early in the course of HIV infection. If a patient's CD4 count is <200 cells/mm^3, or the patient has symptomatic HIV disease, it is preferable to defer vaccination until several months after initiation of antiretroviral (ARV) therapy in an attempt to maximize the antibody response to the vaccine. However, vaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count.

Clinicians should obtain a post-vaccination antibody measurement in patients who are at increased risk for hepatitis A infection, including illicit drug users (see Table 1 in the original guideline document).

Clinicians should periodically readdress vaccination with individuals who initially decline either hepatitis A or hepatitis B vaccination.

Hepatitis B

Clinicians should administer the HBV vaccination series to HIV-infected patients who are negative for HBsAb, unless they are chronically infected.

Clinicians should test for HBsAb between 4 and 12 weeks after vaccination. Nonresponders (HBsAb <10 IU/L) should be revaccinated with another three-dose hepatitis B vaccine series. If a patient's CD4 count is <200 cells/mm^3 or the patient has symptomatic HIV disease, revaccination may be deferred until several

months after initiation of ARV therapy in an attempt to maximize the antibody response to the vaccine. However, revaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count.

For HIV-infected substance users who continue to inject drugs, clinicians should:

- Discuss avoidance of needle/syringe-sharing activity with all injection drug users, regardless of viral load, to prevent HIV and hepatitis B and C virus transmission (See the Table "Viral Hepatitis Risk Reduction Guidance for Substance Users" below)
- Issue prescriptions for new needles and syringes to patients who inject drugs
- Discuss with patients other options for accessing new needles and syringes, including use of the Expanded Syringe Access Demonstration Program and Syringe Exchange Programs, New York State's two syringe access initiatives

Clinicians should advise HIV-infected substance users with chronic hepatitis B infection that drug-sharing, sexual, and household contacts may be at risk for hepatitis B. Such contacts should be advised to undergo medical evaluations and, if susceptible, should be offered HBV vaccination.

Clinicians should evaluate HIV-infected substance users chronically infected with hepatitis B (or co-infected with hepatitis B and C) for liver disease. These patients should be evaluated and offered treatment when medically indicated according to current guidelines (see the National Guideline Clearinghouse [NGC] summary of the New York State Department of Health [NYSDOH] guideline Hepatitis B Virus).

Key Points:

- HBV vaccination is indicated for all HIV-infected substance users who are susceptible and may be particularly important for those co-infected with HCV.
- Advanced immune suppression is not a contraindication to HBV vaccination, and vaccination of susceptible persons should not be deferred or delayed because of advanced immune suppression or in anticipation of expected immune recovery due to the effect of antiretroviral (ARV) therapy.

Hepatitis C

Clinicians should perform annual HCV screening to detect recent infections for HIV-infected substance users who do not have antibody evidence of previous exposure (i.e., who are found to be susceptible to HCV) and who continue to engage in risk behaviors.

HIV-infected substance users who continue to inject substances and who are found to be susceptible to hepatitis C should receive counseling regarding the risk of HCV infection from non-sterile injection practices. These patients should be referred to sources of sterile injection equipment, such as Expanded Syringe Access Demonstration Program and Syringe Exchange Programs, New York State's two syringe access initiatives.

Clinicians should evaluate HIV-infected substance users with chronic hepatitis C infection (or with hepatitis B and C co-infection) for liver disease. These patients should be evaluated and offered treatment when medically indicated according to current guidelines.

HIV-infected substance users chronically infected with hepatitis C (or co-infected with hepatitis B and C) should be counseled to avoid sharing injection equipment or engaging in unprotected sex because their partners will then be at risk for transmission of both HIV and viral hepatitis.

Substance-sharing contacts should be advised to undergo medical evaluations. As part of this medical evaluation, all contacts should be offered testing for HIV and hepatitis C.

Clinicians should advise HIV/HCV co-infected patients and patients infected with HCV alone to discontinue consumption of alcohol.

Key Point:

HCV seems to be more easily transmitted parenterally than HIV.

Prevention

Table: Viral Hepatitis Risk Reduction Guidance for Substance Users

- Stop using illicit drugs - substance users who wish to stop using drugs should be referred to substance abuse treatment when indicated.
- If unable to stop using illicit drugs, substance users should stop injection of illicit drugs.
- If unable to stop injection of illicit drugs, substance users should use a new, sterile needle for every injection.
- Substance users should use their own needle, syringe, filtration cotton, and cooker, without sharing with others.
- If assisting others with injections, the substance user should wash hands thoroughly between injections and use all new equipment.
- Substance users should know their own HIV, hepatitis B, and hepatitis C status, should not engage in unprotected sex, and should be advised to avoid sharing injection equipment.

Effect of Substance Use and Substance Use Treatment on HCV Disease Progression and Treatment

Key Point:

Clinicians should be guided by patients' symptoms (e.g., opioid craving or oversedation) when considering whether a change in methadone or buprenorphine dose is indicated.

Treatment and Adherence

Key Point:

Adherence to the HCV treatment regimen is difficult for all patients, not just substance users or those with HIV. Identification of potential barriers and consideration of measures to promote adherence are essential.

Tuberculosis (TB)

Clinicians should obtain a TST (tuberculin skin test, commonly known as purified protein derivative [PPD]) or other U.S. Food and Drug Administration (FDA)-approved test for diagnosis of tuberculosis infection, unless the patient has previously tested positive or has had previously documented TB.

For patients with a new positive TB test, clinicians should obtain a detailed history, perform a physical examination, and obtain a chest x-ray to determine whether active TB is present.

After active TB has been excluded, clinicians should prescribe TB treatment when a TST results in induration of $\geq$5 mm or when another FDA-approved test indicates the presence of latent TB infection (LTBI).

HIV-infected substance users with active TB should receive expedited treatment and should be enrolled into directly observed therapy (DOT).

Clinicians should evaluate HIV-infected substance users who have LTBI, and, in the absence of medical contraindications or previous completion of preventive therapy, these patients should be offered treatment for LTBI.

Key Points:

- Rifampin may increase the catabolism of opioids and can precipitate opioid withdrawal in opioid users or those on methadone maintenance regimens unless methadone doses are increased.
- Co-locating TB services may improve adherence and rates of treatment completion.

Sexually Transmitted Infections (STIs) in HIV-Infected Substance Users

Clinicians should reinforce behavioral risk-reduction measures for STI prevention, including consistent condom use.

Key Point:

Primary care clinicians play an important role in reinforcing behavioral risk-reduction measures.

Screening for STIs in HIV-Infected Substance Users

Clinicians should screen HIV-infected substance-using patients for syphilis by obtaining a nontreponemal test (rapid plasma reagin [RPR] test or Venereal Disease Research Laboratory [VDRL]) with verification of reactive tests by confirmatory fluorescent treponemal antibody-absorption (FTA-Abs) or *T. pallidum* particle agglutination (TP-PA) at baseline and at least annually. Patients with continued high-risk behavior should be screened for syphilis every 3 months.

Clinicians should screen all sexually active HIV-infected substance-using women for gonorrhea and chlamydia at baseline and at least annually at all sites of exposure, including the cervix, rectum, and pharynx. Culture or nucleic acid amplification tests (NATs) should be used to screen for gonorrhea. Immunofluorescence or DNA amplification should be used for chlamydia.

Clinicians should screen HIV-infected substance-using men who have sex with men for gonorrhea and chlamydia at baseline and at least annually. Clinicians should screen all sites of exposure, including the urethra, rectum, and pharynx.

Soft-Tissue Disorders

Clinicians should counsel intravenous drug users (IDUs) on risk reduction for soft-tissue infections (see Tables 4 and 5 in the original guideline document).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate primary care of the human immunodeficiency virus (HIV)-infected substance user

POTENTIAL HARMS

- Patients actively using alcohol or injecting drugs may experience increased toxicity from hepatitis C (HCV) therapies.
- Rifampin may increase the catabolism of opioids and can precipitate opioid withdrawal in opioid users or those on methadone maintenance regimens unless methadone doses are increased.

- Rifampin may also increase the catabolism of certain protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NRTIs).
- False-positive syphilis nontreponemal tests can occur in intravenous drug users (IDUs) and persons with human immunodeficiency virus (HIV), hepatitis B virus (HBV), and HCV, which emphasizes the importance of also performing treponemal tests.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative, the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center for providers who lack internet access.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2009 Feb. 16 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 (revised 2009 Feb)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Substance Use Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Aspects of primary care for the HIV-infected substance user. New York (NY): New York State Department of Health; 2004. 17 p. [36 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

AVAILABILITY OF COMPANION DOCUMENTS

This guideline is also available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 2, 2005. This NGC summary was updated by ECRI Institute on January 1, 2010.

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